BLA 761143/S-023

**SUPPLEMENT APPROVAL**

Horizon Therapeutics Ireland DAC
c/o Horizon Therapeutics USA Inc
Attention: Fred Henry, MS, MPH
Senior Director, Regulatory Affairs
1 Horizon Way
Deerfield, IL 60015

Dear Fred Henry:

Please refer to your supplemental biologics license application (sBLA), dated and received January 20, 2023, and your amendments, submitted under section 351(a) of the Public Health Service Act for TEPEZZA (teprotumumab-trbw) for injection. This Prior Approval sBLA provides for additions to the WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and PATIENT COUNSELING INFORMATION sections of the Prescribing Information.

## APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,[1] that is identical to the enclosed labeling (text for the Prescribing Information) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible via publicly available labeling repositories.

## REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

If you have any questions about this supplement, call Derek Alberding, Clinical Analyst, at (240) 402-0963.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, MD
Director
Division of Ophthalmology
Office of Specialty Medicine
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
    - Prescribing Information

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/

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07/17/2023 03:50:00 PM